

### **REMARKS/ARGUMENTS**

Regarding the Non-final Office Action dated 09/07/2006, Applicant respectfully requests that claim 10 be canceled and claims 1, 3, 11, 12, 17, 21, 23, 24 and 25 be amended as indicated above in the Listing of Claims, and that the following remarks and arguments be considered.

Applicant asserts that the claims as amended comply with 37 C.F.R. §1.116 such that they are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

#### **I. Drawings**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because the character “20c” is alleged to designate both shank and heat-staking end.

Applicant submits that it is not the drawings that are mislabeled, but rather the Specification, which at paragraph 0031 incorrectly designates the “staked end 20c” as the “shank 20c.” Paragraph 0031 of the Specification has been amended to remove this error. Applicant respectfully asserts that the Figures are correct and do not need amendment. Applicant therefore requests reconsideration in light of the amendment to paragraph 0031, and withdrawal of this objection.

#### **II. Specification**

The Examiner notes that the trademarked word “Silastic” should be capitalized in the application and accompanied by the generic terminology. Therefore, Applicant has amended paragraphs 0030, 0033, 0040 and 0043, to capitalize the word Silastic and to explain that this term comes from the combination of the words silicone and elastomer. That is, “Silastic” is a neologism created from fused parts of “silicone” and “elastomer” to give a combined meaning. “Dow Corning Silastic, medical grade” is a brand of Silastic. Applicant requests reconsideration in light of the amendments to paragraphs 0030, 0033, 0040 and 0043.

#### **III. Claim Objections**

Claim 3 is objected to because the Examiner suggests that the phrase “low-modulus” should be included when referring to silicone sheet material, as in claims 9 and 22. For

consistency, Applicant has amended claim 3 to include this phrase, and requests withdrawal of this rejection in light of this amendment.

**Claim Rejections – 35 USC §112, first paragraph**

Claims 1, 3, 4, 7-12, 16, 17, 21-25 are rejected under 35 USC §112, first paragraph, for allegedly failing to comply with the written description requirement and adding new matter (MPEP 608.04). Specifically, the Examiner asserts that claims 1, 10, 11, 21, 23 and 25 now recite the claim limitation of the second valve unit begins to open at “*greater than*” or “*beyond*” 3 cm of water, but the original disclosure does not show this. See page 12, para. 0045 (“about” 3cm), and p. 4, para. 0020, and p.9, para.0036, and p. 12, para. 0045 (“about” 4 cm). “About” gives range of 2.5-3.3 cm, while “*greater than*” limits opening to 3.0 and greater.

Applicant has amended claims 1, 10, 11, 21, 23 and 25 to cancel this alleged new matter from the claims, and to clarify that the second valve begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration reaches “*about*” 3 cm of water, as originally disclosed in the application as filed. Thus, Applicant respectfully requests that the rejection of claims 1, 3, 4, 7-12, 16, 17, 21-25 be withdrawn and the claims, as amended, be reconsidered and allowed.

**IV. Claim Rejections – 35 USC §112, second paragraph**

Claims 1, 3, 4, 7-12, 16, 17, 21-25 are rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claims 1, 10, 11, 21 and 23 now recite that the second valve blocks airflow at “less than about 3 cm” (p. 4, para. 0018) or “less than about 4 cm” (p. 4, para. 0020), such that the scope is inherently broad and must be corrected and clarified. More specifically, the Examiner points out that claims 1, 7, 12, 16, 17, 21 and 23-25 now recite the claim limitation directed only toward the second valve consisting of a slit valve or the second valve consisting of an umbrella valve. The Examiner asserts that Applicant has disclosed that the slit valve begins to open at about 4 cm of water and is fully open at about 10 cm of water (p. 9, para. 0036); while the umbrella valve begins to open at about 3 cm or 4 cm of water, depending on the embodiment, and the valve is fully open at about 12 cm of water,

typically about 10 cm (p. 12, para. 0045), such that the recitation of when the valve is “fully open” is separate and distinct as the umbrella valve may or may not be “fully open” at 10 cm of water. As a result of this discrepancy in the specification, the Examiner asserts that independent claims 1 and 21, which recite “intrathoracic pressure during expiration is...3 cm of water” is only supported by the umbrella valve (p. 12, para. 0045), such that claims 7, 10, 11, 12, 16, 17, 21, 23-25 are improper for reciting limitations of a slit valve. The Examiner also states that the limitation in claims 10, 11, 12, 16, 17, 23-25, which recite that the second valve is “fully open when the intrathoracic pressure reaches about 10 cm of water,” is only supported by the slit valve (p. 9, para. 0036), such that these dependent claims do not have limitations associated with an umbrella valve.

Applicant has canceled claim 10 and amended claims 1, 12, 17, 21, 23 and 24 in order to correct and clarify the scope and operational characteristics of the second valve, as it applies to both a slit valve and an umbrella valve, according to the distinct limitations on p. 9, para. 0036 and p. 12, para. 0045. Specifically, independent claims 1 and 21 have been amended to indicate that the second valve blocks airflow when the intrathoracic pressure during expiration is less than about 4 cm of water. This limitation is consistent with both a slit valve and an umbrella valve. In light of the amendment to claim 1, Applicant asserts that claim 7 need not be amended. Applicant has canceled claim 10 because the limitations set forth in canceled claim 10 were not consistent for both a slit valve and an umbrella valve, as disclosed in the original specification. Claims 12, 17, 23 and 24 have been amended to indicate that the limitations claimed therein are only consistent with a slit valve. In light of these amendments, Applicant respectfully requests that the rejection of claims 1, 3, 4, 7-12, 16, 17, 21-25 be withdrawn and the claims, as amended, be reconsidered and allowed.

**CONCLUSION**

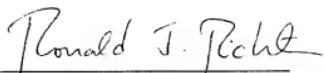
Applicant has addressed each point raised in the Non-final Office Action dated 09/07/2006 in the present Response, and respectfully requests reconsideration of the present application in view of the foregoing amendments and remarks, that the rejection of the claims be withdrawn, that claim 10 be canceled and that remaining claims 1, 3, 4, 7-9, 11, 12, 16, 17 and 21-25 be duly allowed.

The Examiner is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

Respectfully submitted,

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